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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,719	08/28/2003	Kenji Nakajima	Q77115	6178
23373 7590 01/17/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER LAM, ANN Y	
			ART UNIT 1641	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/649,719

**Applicant(s)**

NAKAJIMA, KENJI

**Examiner**

Ann Y. Lam

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2-4, 15, 16 and 19 is/are rejected.
- 7) ☒ Claim(s) 17 and 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-4, 15, 16 and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/692,011, in view of Decker et al., 4,230,683.

Application No. 10/692,011 recites the limitations substantially as claimed (see claims 1-9), except for the receptor being labeled with an enzyme, nor that the enzyme is part of an enzyme-labeled antibody wherein the enzyme-labeled antibody is subjected to

specific binding with the labeled receptor. Decker et al. however teach this specific type of assay.

Decker et al. teach an improvement in an immunoassay comprising the steps of reacting an antigen bound to a solid support with a hapten/conjugated antibody to the antigen, further reacting hapten conjugated antibody bound to the solid support with labeled anti-hapten antibody and determining the labeled antibody bound to the solid support (col. 1, lines 59-64). Decker et al. teach that the invention makes use of hapten conjugated antibodies to amplify antigenicity of the bound antibody. Each hapten conjugated antibody will have several hapten molecules bound thereto providing for multiplication of the antigenic reactivity (col. 2, lines 59-63). Moreover, Decker et al. teach that methods for directly or indirectly binding antigens or antibodies to be detected to a solid support are well known (col. 1, lines 7-11, and lines 38-40). Decker et al. also teach that the use of labeled antibodies (i.e., labeled with enzymes for example) in solid phase immunoassay is well known (col. 2, lines 43-45).

As to claim 19, Applicant claims in the present application that the liquid containing the labeled receptor is caused to flow across the adsorptive regions at a different time from when the enzyme-labeled antibody is caused to flow across the adsorptive regions. While Decker et al. disclose the reagents mentioned above and performing the assay by allowing the reagents to react respectively with each other, there is no specific disclosure of flowing the two liquids mentioned above at different times. However, it is predictable by the skilled artisan that the reagents mentioned above may be flowed at different times, as such flowing will also allow for the reactions

to occur and thus the assay to be performed. Such predictability renders the steps obvious.

It would have been obvious to one ordinary skill in the art at the time the invention was made to perform the Decker et al. immunoassay using the invention claimed by Application No. 10/692,011 because Decker et al. teach that the immunoassay as disclosed, including use of hapten/conjugated antibody, provides an improvement of the immunoassay because it amplifies the antigenic reactivity of the immunoassay. One of ordinary skill in the art would be motivated to utilize the improved immunoassay as the particular assay performed using the method recited in Application No. 10/692,011 for its amplified detection, as would be desirable for more accurate results.

This is a provisional obviousness-type double patenting rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3, 15-16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipwash, 6,846,638, in view of Decker et al., 4,230,683.

Shipwash discloses the invention substantially as claimed.

More specifically, as to claim 1, Shipwash discloses a chemical luminescence method (col. 26, lines 20-23, and col. 19, lines 50-55) comprising the steps of:

i) obtaining a biochemical analysis unit (i.e., microarray and microfluidic system in col. 21, lines 52-53) provided with a plurality of porous adsorptive regions (col. 40, line 63 – col. 41, line 3, disclosing beads made of porous resins for immobilizing proteins or nucleic acids), (the porous resins, or alternatively, the regions containing the porous resins, are considered to be a plurality of adsorptive regions), to which ligands (i.e., the immobilized proteins in col. 37, line 6) have been bound respectively,

ii) subjecting a receptor (i.e., the particular molecule to which the immobilized proteins bind, see col. 10, lines 48-54 and 60-61 and 66-67) to specific binding with the ligands, the receptor being thereby specifically bound to the ligands [forming a ligand-receptor complex],

iii) providing a label to the ligand-receptor complex (see col. 26, line 21, disclosing an enzyme label to achieve chemiluminescence with a substrate; and see col. 19, lines 50-55, disclosing that labels may be attached to a member of a binding complex),

iv) causing a chemical luminescence substrate (e.g., luminol substrate, col. 26, lines 20-33) to undergo a reaction with the enzyme-labeled antibody, which has been specifically bound to the labeled receptor or the labeled ligand,

wherein, a reaction liquid containing the enzyme label is forcibly caused to flow across each of the porous adsorptive regions of the biochemical analysis unit (col. 28, line 66 – col. 29, line 23, disclosing, in general, microflow through microchannels for

incubation and washing steps, and a pump; and see also col. 21, lines 23-41, disclosing pumps in microfluidic systems).

While Shipwash discloses that in general binding assays may utilize the binding between an immobilized protein to recognize an analyte to which it binds and that enzymes for chemiluminescence detection can be used, Shipwash however does not teach the particular binding assay disclosed by Applicant.

More specifically, Shipwash does not disclose that the receptor is labeled, nor that the enzyme is part of an enzyme-labeled antibody wherein the enzyme-labeled antibody is subjected to specific binding with the labeled receptor. Decker et al. however teach this specific type of assay.

Decker et al. teach an improvement in an immunoassay comprising the steps of reacting an antigen bound to a solid support with a hapten/conjugated antibody to the antigen, further reacting hapten conjugated antibody bound to the solid support with labeled anti-hapten antibody and determining the labeled antibody bound to the solid support (col. 1, lines 59-64). Decker et al. teach that the invention makes use of hapten conjugated antibodies to amplify antigenicity of the bound antibody. Each hapten conjugated antibody will have several hapten molecules bound thereto providing for multiplication of the antigenic reactivity (col. 2, lines 59-63). Moreover, Decker et al. teach that methods for directly or indirectly binding antigens or antibodies to be detected to a solid support are well known (col. 1, lines 7-11, and lines 38-40). Decker et al. also teach that the use of labeled antibodies (i.e., labeled with enzymes for example) in solid phase immunoassay is well known (col. 2, lines 43-45).

It would have been obvious to one ordinary skill in the art at the time the invention was made to perform the Decker et al. immunoassay using the Shipwash assay device because Decker et al. teach that the immunoassay as disclosed, including use of hapten/conjugated antibody, provides an improvement of the immunoassay because it amplifies the antigenic reactivity of the immunoassay. One of ordinary skill in the art would be motivated to utilize the improved immunoassay as the particular assay performed using the Shipwash assay device for its amplified detection, as would be desirable for more accurate results. Moreover, one of ordinary skill in the art would have reasonable expectation of success because Decker et al. teach that methods for directly binding antigens or antibodies to a solid support, such as the Shipwash solid support, are well known in the art. Moreover, Shipwash disclose that assays that utilize enzymes as labels may be utilized with the assay device, and thus one of ordinary skill in the art would have reasonable expectation of success in performing the assay taught by Decker et al. utilizing enzymes as labels.

Thus, in performing the Decker et al. assay method using the Shipwash assay device, the antigens bound to the solid support as disclosed by Decker et al. in column 1, lines 59-60 is considered to be the bound ligands recited by Applicant in claim 1, line 4. The hapten/conjugated antibody as disclosed by Decker in column 1, lines 60-61 is considered to be the labeled receptor recited by Applicant in claim 1, line 6. The enzyme labeled anti-hapten antibody as disclosed by Decker in column 1, line 63 is considered to be the enzyme-labeled antibody recited by Applicant in claim 1, line 13. Thus, in the combination of Decker et al. and Shipwash, the step of contacting the



labeled receptor with the bound ligands, as taught by Decker et al., is one of the incubation steps, that is flowed through the microchannels via a pump in the Shipwash device. At a time at which the enzyme-labeled antibody is subjected to binding with the labeled receptor, a liquid containing the enzyme-labeled antibody is forcibly caused to flow across each of the beads or regions of beads because the step of contacting, allowing for binding, is performed by flowing via a pump. Stated another way, in the modification of the Shipwash invention as mentioned above, the skilled artisan would use the Shipwash device, with the adsorptive materials, for applying the Decker et al. assay reagents to perform the assay disclosed by Decker et al., which therefore includes the two reactions liquids mentioned above, and thus in turn these two reaction liquids would be forcibly caused to flow through the adsorptive regions of the Shipwash device as the Decker et al. assay is carried out. The Office notes that Applicant has not claimed which element is an analyte intended to be detected.

As to the limitations in claim 3 regarding a reaction liquid containing the labeled receptor being forcibly caused to flow such that the reaction liquid containing the labeled receptor flows across each of the porous adsorptive regions is disclosed as follows. Shipwash discloses in general microflow through microchannels for incubation and washing steps, and a pump (see col. 28, line 66 – col. 29, line 23; and also col. 20, col. 21, lines 23-41). Moreover, Decker et al. teach an assay using a labeled receptor (i.e., hapten/conjugated antibody) as described above. Thus, in the combination of the teachings of the Decker et al. assay using the Shipwash assay device (as discussed previously above), the step of contacting the labeled receptor with the bound ligands, as

taught by Decker et al., is one of the incubation steps, that is flowed through microchannels via a pump in the Shipwash device, and thus the labeled receptor is forcibly flowed via a pump to porous adsorptive regions (solid support) in the Shipwash device where it binds to the ligands. (That is, at a time at which the labeled receptor is subjected to binding with the ligand, a liquid containing the labeled receptor is forcibly caused to flow across each of the beads or regions of beads because the step of contacting, allowing for binding, is performed by flowing via a pump.)

As to claim 15, the reaction liquid containing the labeled receptor or the labeled ligand (as disclosed by Decker et al. as described above) is forced to flow into an interior of each of the porous adsorptive regions of the biochemical analysis unit (the beads in Shipwash are porous—see col. 40, line 67 – col. 41, line 2--and thus the fluids in Shipwash flows into the interior of the beads.)

As to claim 16, Applicant recites that the method further comprises photoelectrically detecting the bound labeled receptor. As noted earlier, the labeled receptor is disclosed by Decker et al., the label being disclosed in general as those well known in the art, for example enzymes and fluorescent chemicals, (see col. 2, lines 43-45; and see also col. 1 lines 49-52). Shipwash disclose that labels for use in the invention include enzymes that produce luminescent or electrogenic products (col. 60, lines 6-21), and that the labels will be detected in a manner appropriate to their nature, and optical detection methods including CCD cameras are commonly employed for detection (col. 32, lines 49-57). It would have been obvious to one of ordinary skill in the art to utilize an enzyme label that produces luminescent or electrogenic products as the

enzyme label in the Decker et al. method, because Decker et al. do not limit the label to any particular label but rather disclose that enzyme labels well known in the art may be used, and the Shipwash primary reference disclose that such known enzyme labels are those that produce luminescent or electrogenic products. Moreover, the skilled artisan would utilize the CCD camera for detection, as taught by Shipwash, because Shipwash teaches that the labels will be detected in a manner appropriate to their nature and the skilled artisan would recognize that the luminescent product of the enzyme label is detectable by a CCD camera. (It is noted that Applicant's specification disclose that a CCD camera is utilize for photoelectrically detecting.)

As to claim 19, Applicant claims that the liquid containing the labeled receptor is caused to flow across the adsorptive regions at a different time from when the enzyme-labeled antibody is caused to flow across the adsorptive regions. While Decker et al. disclose the reagents mentioned above and performing the assay by allowing the reagents to react respectively with each other, there is no specific disclosure of flowing the two liquids mentioned above at different times. However, it is predictable by the skilled artisan that the reagents mentioned above may be flowed at different times, as such flowing will also allow for the reactions to occur and thus the assay to be performed. Such predictability renders the steps obvious.

Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipwash, 6,846,638, in view of Decker et al., 4,230,683, and further in view of Woias et al., 6,490,034.

Shipwash in view of Decker et al. disclose the invention substantially as claimed (the discussion above regarding steps (i) through (iv) in claim 3 is also applicable to claim 2). However, Shipwash and Decker et al. do not disclose the step of ceasing fluid flow as recited in claims 2 and 4. However, Woias et al. teach the motivation to cease fluid flow.

Woias et al. teach an assay device with an inlet and an outlet and a pump that stops flow of fluid. Woias et al. teach that the device is adapted to be used in a very flexible manner, and that when an inlet and an outlet opening are provided, "stopped-flow" operation is possible. The reagent is pumped in, whereupon the pump is stopped and the reaction is allowed to take place (col. 4, lines 39-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to stop flow of fluid as taught by Woias et al. during performance of the Decker et al. assay utilizing the Shipwash assay device because Woias et al. teach that stopping flow of fluid allows for the reaction to take place. One of ordinary skill in the art would recognize the benefits of stopping a pump to allow for a reaction to take place as taught by Woias et al. as it provides for more thorough completion of reaction.

Moreover, one of ordinary skill in the art would have reasonable expectation of success because Woias et al. teach that an assay device with an inlet and an outlet, and a pump, would allow for a stopped-flow operation, permitting a reaction to take

place. Because the Shipwash device has a pump as well as an inlet and outlet (see for example, column 3, line 19; and see for example column 29, lines 18-19), one of ordinary skill in the art would have reasonable expectation of success in stopping the Shipwash pump to allow the reaction to take place.

More specifically, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the Decker et al. assay using the Shipwash device such that after the reaction liquid containing the enzyme-labeled antibody has been forcibly caused to flow such that the reaction liquid flows across each of the porous adsorptive regions of the biochemical analysis unit, the forcible flowing is ceased during a period of time longer than the time during which the reaction liquid containing the enzyme-labeled antibody has been forcibly caused to flow, because Woias et al. teach that stopping flow allows for the reaction to take place.

Moreover, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (MPEP 2144.05 IIA, citing *In re Aller*, 1-5 USPQ 233.) In this case, stopping the flow of enzyme-labeled antibody for a period of time longer than the period of time during which the reaction liquid containing the enzyme-labeled antibody has been forcibly caused to flow appears to be an optimum or workable range and thus, its discovery involves only routine skill in the art.

***Allowable Subject Matter***

Claim 1 is allowed.

Claims 17 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach a method including obtaining a unit with a plurality of porous adsorptive regions and causing flow of materials across the porous adsorptive regions, wherein receptors or ligands on the adsorptive regions are spotted onto the adsorptive regions.

***Response to Arguments***

Applicant's arguments filed October 16, 2007 have been fully considered but they are not persuasive.

Applicant argues that as to claim 3, Shipwash does not disclose or suggest forcibly flowing different reaction liquids at two times, i.e., the reaction liquid containing the labeled receptor or the labeled ligand is forcibly caused to flow across each of the porous adsorptive regions and the reaction liquid containing the enzyme-labeled antibody is forcibly caused to flow across each of the porous adsorptive regions. Examiner acknowledges that Applicant is correct that the claim requires forcibly flowing different reaction liquids at two times. However Applicant's argument is not persuasive

because, as indicated in the grounds for rejection, it is acknowledged that Shipwash does not teach the particular binding assay disclosed by Applicant, specifically that the receptor is labeled, and that the enzyme is part of an enzyme-labeled antibody wherein the enzyme-labeled antibody is subjected to specific binding with the labeled receptor. However, this type of assay is disclosed by Decker et al. In the modification of the Shipwash invention, the skilled artisan would use the Shipwash device, with the adsorptive materials, for applying the Decker et al. assay reagents to perform the assay disclosed by Decker et al., which therefore includes the two reactions liquids mentioned above, and thus in turn these two reaction liquids would be forcibly caused to flow through the adsorptive regions of the Shipwash device as the Decker et al. assay is carried out.

As to claim 2, Applicant argues that stopping the forcible flow for a period of time longer than the forcible flow allows for optimum detection of the labeled receptor or the labeled ligand with a low amount of labeled receptor or the labeled ligand, and accordingly the stopping time is not simply an optimum workable range but one of the many unique features of the present invention. This is not persuasive because, as discussed in the grounds for rejection, Woias et al. teach that stopping flow allows for the reaction to take place, and as would be readily recognized and predictable to the skilled artisan, stopping the flow for a period longer than the forcible flow allows for the reaction to occur. In other words, Woias suggests the desirability of allowing for the reaction to take place by stopping flow, and the skilled artisan would recognize that stopping the flow for a period of time longer than the forcible flow would allow for the

reaction to take place. Such period of stopping is thus within an optimum or workable range. Moreover, such period of stopping which allows for the reaction to occur also in turn allows for optimum detection, as mentioned by Applicant. Such period of stopping thus falls within an optimum range, and discovering such an optimum period involves only routine skill in the art (MPEP 2144.05 IIA, citing *In re Aller*, 1-5 USPQ 233.)

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.




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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Ann Y. Lam  
Primary Patent Examiner